

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michelle M. Hanna

Appl. No. *To Be Assigned (Div. of Appl.
No. 09/984,664; Filed: October 30, 2001)*

Filed: Herewith

For: **Molecular Detection Systems
Utilizing Reiterative
Oligonucleotide Synthesis**

Confirmation No.

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 2072.0010003/LBB/SJE

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application

does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
 - ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form **[OR]** Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version

of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

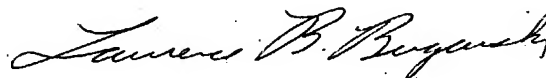
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/984,664, filed October 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky
Attorney for Applicant
Registration No. 35,086

Date: June 24, 2003

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Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2072.0010002/LBB/SJE	APPLICATION NO. To Be Assigned (Div. of 09/984,664; Filed: October 30, 2001)
	APPLICANT HANNA, Michelle M.	
	FILING DATE Herewith (June 24, 2003)	GROUP To Be Assigned

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	3,996,345	12/1976	Ullman et al.			
	AB1	4,351,760	09/1982	Khanna et al.			
	AC1	4,582,788	04/1986	Erlich			
	AD1	4,683,194	07/1987	Saiki et al.			
	AE1	4,739,044	04/1988	Stabinsky			
	AF1	4,757,141	07/1988	Fung et al.			
	AG1	4,786,600	11/1988	Kramer et al.			
	AH1	5,130,238	07/1992	Malek et al.			
	AI1	5,169,766	12/1992	Schuster et al.			
	AJ1	5,508,178	04/1996	Rose et al.			
	AK1	5,595,891	01/1997	Rose et al.			

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1						Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
	AP1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	1	Agrawal, S., and Tang, J.-Y., "Site-specific functionalization of oligodeoxynucleotides for non-radioactive labeling," <i>Tetrahedron Lett.</i> 31:1543-1546, Pergamon Press (1990)	
AS	1	Chamberlin, M.J., "Bacterial DNA-Dependent RNA Polymerases," in <i>The Enzymes</i> , Boyer, P.D., ed., Academic Press, New York, N.Y. pp. 61, 84-86 (1982)	
AT	1	Costas, C., et al., "RNA-protein crosslinking to AMP residues at internal positions in RNA with a new photocrosslinking ATP analog," <i>Nucleic Acids Res.</i> 28:1849-1858, Oxford University Press (May 2000)	

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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	AA2	5,648,211	07/1997	Fraiser et al.			
	AB2	5,654,142	08/1997	Kievits et al.			
	AC2	5,679,512	10/1997	Laney et al.			
	AD2	5,683,879	11/1997	Laney et al.			
	AE2	5,744,308	04/1998	Guillou-Bonnici et al.			
	AF2	5,766,849	06/1998	McDonough et al.			
	AG2	5,824,517	10/1998	Cleuziat et al.			
	AH2	5,858,801	01/1999	Brizzolara			
	AI2	6,008,334	12/1999	Hanna			
	AJ2	6,107,037	08/2000	Sousa et al.			
	AK2	6,107,039	08/2000	Hanna			

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	2	Daube, S.S., and von Hippel, P.H., "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Duplexes," <i>Science</i> 258:1320-1324, American Association for the Advancement of Science (1992)
	AS	2	Dunn, J.J., and Studier, F.W., "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements," <i>J. Mol. Biol.</i> 166:477-535, Academic Press, Inc. (1983)
	AT	2	Gait, M.J., et al., "Oligoribonucleotide synthesis," in <i>Oligonucleotides and Analogues</i> , Eckstein, F., ed., Oxford University Press, Oxford, Great Britain, pp. 25-31 (1992)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>3</u>	Gait, M.J., "An Introduction to Modern Methods of DNA Synthesis," in <i>Oligonucleotide synthesis: a practical approach</i> , Gait, M.J., ed., Oxford University Press, Oxford, Great Britain, pp.1-22 (1984)
AS	<u>3</u>	Geider, K., et al., "An RNA transcribed from DNA at the origin of phage fd single strand to replicative form conversion," <i>Proc. Natl. Acad. Sci. USA</i> 75:645-649, National Academy Press (1978)
AT	<u>3</u>	Guatelli, J.C., et al., "Isothermal, in vitro amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication," <i>Proc. Natl. Acad. Sci. USA</i> 87:1874-1878, National Academy Press (1990)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Gupta, K.C., et al., "A general method for the synthesis of 3'-sulfhydryl and phosphate group containing oligonucleotides," <i>Nucleic Acids Res.</i> 19:3019-3025, Oxford University Press (1991).
	AS	4	Gurevich, V.V., et al., "Preparative in Vitro mRNA Synthesis Using SP6 and T7 RNA Polymerases," <i>Anal. Biochem.</i> 195:207-213, Academic Press, Inc. (1991)
	AT	4	Hanna, M.M., "Photoaffinity Cross-Linking Methods for Studying RNA-Protein Interactions," <i>Methods Enzymol.</i> 180:383-409, Academic Press, Inc. (1989)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>5</u>	Hanna, M.M., et al., "Probing the environment of nascent RNA in <i>Escherichia coli</i> transcription elongation complexes utilizing a new fluorescent ribonucleotide analog," <i>Nucleic Acids Res.</i> 27:1369-1376, Oxford University Press (1999)
	AS	<u>5</u>	Hanna, M.M., et al., "Synthesis and characterization of a new photocrosslinking CTP analog and its use in photoaffinity labeling <i>E.coli</i> and T7 RNA polymerases," <i>Nucleic Acids Res.</i> 21:2073-2079, Oxford University Press (1993)
	J AT	<u>5</u>	He, B., et al., "Preparation of probe-modified RNA with 5-mercapto-UTP for analysis of protein-RNA interactions," <i>Nucleic Acids Res.</i> 23:1231-1238, Oxford University Press (1995)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Kwoh, D.Y., et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <i>Proc. Natl. Acad. Sci. USA</i> 86:1173-1177, National Academy Press (1989)
	AS	6	Lewis, M.K., and Burgess, R.R., "Transcription of Simian Virus 40 DNA by Wheat Germ RNA Polymerase II," <i>J. Biol. Chem.</i> 255:4928-4936, American Society for Biochemistry and Molecular Biology (1980)
	AT	6	Martin, C.T., et al., "Processivity in Early Stages of Transcription by T7 RNA Polymerase," <i>Biochemistry</i> 27:3966-3974, American Chemical Society (1988)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	7	Meyer, K.L., and Hanna, M.M., "Synthesis and Characterization of a New 5-Thiol-Protected Deoxyuridine Phosphoramidite for Site-Specific Modification of DNA," <i>Bioconjugate Chem.</i> 7:401-412, American Chemical Society (1996)
	AS	7	Milligan, J.F., and Uhlenbeck, O.C., "Synthesis of Small RNAs Using T7 RNA Polymerase," <i>Methods Enzymol.</i> 180:51-62, Academic Press, Inc. (1989)
	AT	7	Montemagno, C., and Bachand, G., "Constructing nanomechanical devices powered by biomolecular motors," <i>Nanotechnology</i> 10:225-231, IOP Publishing, Ltd. (1999)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>8</u>	Mullis, K., et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," Cold Spring Harb. Symp. Quant. Biol. 51:263-273, Cold Spring Harbor Laboratory (1986)
	AS	<u>8</u>	Mullis, K.B., et al., "The Polymerase Chain Reaction: Why It Works," in Polymerase Chain Reaction, Erlich, H.A., et al., eds., Cold Spring Harbor Laboratory Press, Woodbury, N.Y., pp. 237-243 (1989)
	AT	<u>8</u>	Nelson, P.S., et al., "Bifunctional oligonucleotide probes synthesized using a novel CPG support are able to detect single base pair mutations," Nucleic Acids Res. 17:7187-7194, Oxford University Press (1989)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>9</u>	Pringsheim, P., "Fluorescence of organic compounds," in Fluorescence and phosphorescence, Pringsham, P., ed., Interscience Publishers, Inc. New York, N.Y., pp. 392-397, 420-423 (1949)
	AS	<u>9</u>	Saiki, R.K., et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," <i>Science</i> 239:487-491, American Association for the Advancement of Science (1988)
	AT	<u>9</u>	Sinha, N.D., and Striepeke, S., "Oligonucleotides with reporter groups attached to the 5'-terminus," in <i>Oligonucleotides and Analogues: A Practical Approach</i> , Eckstein, F., ed., Oxford University Press pp. 185-189, 200-201 (1992)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>10</u>	Smithies, O., et al., "Detection of Targeted Gene Modifications by Polymerase Chain Reaction," in Polymerase Chain Reaction, Erlich, H.A., et al., eds., Cold Spring Harbor Laboratory Press, Woodbury, N.Y., pp. 199-203 (1989)
	AS	<u>10</u>	Sproat, B.S., et al., "The synthesis of protected 5'-mercapto-2',5'-dideoxyribonucleoside-3'-O-phosphoramidites; uses of 5'-mercapto-oligodeoxyribonucleotides," Nucleic Acids Res. 15:4837-4848, Oxford University Press (1987)
	AT	<u>10</u>	Walker, G.T., et al., "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system," Proc. Natl. Acad. Sci. USA 89:392-396, National Academy Press (1992)

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	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	11	Zuckermann, R., et al., "Efficient methods for attachment of thiol specific probes to the 3'-ends of synthetic oligodeoxyribonucleotides," <i>Nucleic Acids Res.</i> 15:5305-5321, Oxford University Press (1987)
AS		Daube et al., "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Complexes," <i>Science</i> , 1992, vol. 258, pages 1320-1324
AT		Mancini et al., "Constitutively Methylated CpG Dinucleotides as Mutation Hot Spots in the Retinoblastoma Gene (RB1), <i>American Journal of Human Genetics</i> , 1997, vol. 61, pages 80-87

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.